



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,429	06/24/2003	Zifei Wang	A03P1031	4308

36802 7590 10/04/2005

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
----------	--------------

3762

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/603,429

Applicant(s)

WANG ET AL.

Examiner

Michael Kahelin

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 9/23/2005 have been fully considered but they are not persuasive. Applicant argued that the invention disclosed by Stadler et al. (6,381,493) does not anticipate claims 1-4, 7, 13, and 15-20 because Stadler et al.'s invention detects cardiac ischemia based on signals prior to, instead of subsequent to, ventricular repolarization. Because applicant does not define any fiducial point besides ventricular repolarization (T-wave), and because the measured signal is periodic, any point other than a point defining repolarization is before or after said fiducial point. For example, Fig. 5 shows a measured signal subsequent to repolarization (see unlabeled T-wave at left). Therefore, Stadler et al.'s disclosure, in its broadest reasonable sense, anticipates claims 1-4, 7, 13, and 15-20 and the rejections stand. In addition, applicant's argument that the rejections under U.S.C. 103 are moot because of dependence on claim 1 is not persuasive because of the justification above. Thus, the rejections applied to claims 1-20 stand.

Specification

2. The corrected disclosure is accepted.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 7, 13, and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Stadler et al. (6,381,493 B1).
3. In regards to claim 1 and 18, Stadler et al. disclose an implantable medical device comprising receiving electrical signals from the heart with a sensing circuit, identifying segments of the cardiac signal subsequent to ventricular repolarization (Fig. 6, element 2), and detects ischemia based on an examination of the segments (Fig. 6, element 6).
4. In regards to claim 2, Stadler et al. disclose that ischemia is detected to predict myocardial infarction (col. 1, line 45).
5. In regards to claim 3, detecting ischemia is based on detecting a sharp falling edge within the segments following repolarization (col. 18, line 7).
6. In regards to claims 13, 15, and 17, a warning signal is provided to an external device to indicate ischemia (Fig. 1A and col. 8, line 55).
7. In regards to claims 4, 16, 19 and 20, Stadler et al. disclose utilizing a high-pass filtered signal (col. 25, line 41), deriving an energy value (potential energy) following each ventricular repolarization with a running average (col. 26, line 3), inputting a first and second threshold value (col. 26, line 35), and detecting a sharp falling edge based

Art Unit: 3762

on the average value, running average and thresholds (col. 26, line 15). Please note that the examiner interprets a band-pass filter as a high-pass and low-pass filter.

8. In regards to claim 7, Stadler et al. disclose that the energy value consists of summing digitized versions of the filtered signals at a certain start and end time (col. 25, line 52).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler et al. in view of Berger (5,560,368). Stadler et al. disclose the essential features of the claimed invention except for a high-pass filter with a frequency in the range 0.1 to

Art Unit: 3762

5.0 Hz or at least 1.0 Hz. Berger teaches of a method of measuring ECG intervals using a filter with a high-pass cutoff frequency of about 1 Hz (col. 10, line 48) to preserve the repolarization signal. Therefore it would have been obvious to one having ordinary skill in the art at the time of invention to provide a cutoff frequency of 1 Hz to Stadler et al.'s invention to preserve the repolarization signal.

12. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler et al. in view of Fischell et al. (6,609,023 B1). Stadler et al. disclose the essential features of the claimed invention except for defining a start time of $S1 + S_to_S_Interval / 4$ and an end time of $S2 - S_to_S_Interval / 4$. Fischell et al. teach of defining the ST interval based on R-R intervals to ensure that an accurate T-wave signal is acquired, regardless of heart rate (col. 21, line 41). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to define a start time of $S1 + S_to_S_Interval / 4$ and an end time of $S2 - S_to_S_Interval / 4$ for Stadler et al.'s teaching of a R-R interval-based acquisition period. Furthermore, it would be obvious to one having ordinary skill in the art to make a visual estimation of the T-wave interval to provide a heart rate dependent measurement window that requires little computation.

13. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler et al. in view of Park et al. (2003/0153956 A1). Stadler et al. disclose the essential features of the claimed invention except for deriving a running average using the equation as claimed. Park et al. teach of a digital smoothing method using the claimed equation to provide a less noisy signal that can be filtered using bit-shifting instead of arithmetic (par. 0083). Therefore, it would have been obvious to one having

Art Unit: 3762

ordinary skill in the art at the time of invention to derive a running average using the equation as claimed in Stadler et al.'s invention to provide a less noisy signal that can be filtered using bit-shifting instead of arithmetic.

14. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler et al. in view of Beker et al. (2003/0208129 A1). Stadler et al. disclose the essential features of the claimed invention except for determining whether the energy integral minus the running average exceeds the first threshold or the running average exceeds the second threshold and determining whether this value is below both thresholds. Beker et al. teach of a method of signal analysis for ECG signals comprising comparing a current wave with a reference wave (fig. 7, element 116), comparing averaged waves to a threshold (fig. 7, element 124), taking action if both thresholds are exceeded (fig. 7, element 126) and ending if neither threshold is exceeded (fig. 7) to ensure that both individual measurements and average measurements can induce the active state. Therefore, it would have been obvious to someone having ordinary skill in the art at the time of invention to determine whether the energy integral minus the running average exceeds the first threshold or the running average exceeds the second threshold and determine whether this value is below both thresholds with Stadler et al.'s invention to ensure that both individual measurements and average measurements can induce the active state.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler et al. in view of Fischell et al. (6,272,379 B1). Stadler et al. disclose the essential features of the claimed invention except for applying a perceptible electrical notification

Art Unit: 3762

subcutaneously. Fischell et al. teach of an implantable electronic system with a subcutaneous electrical notification system to warn a patient of heart dysfunction (col. 1, line 47). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply Fischell et al's subcutaneous electrical notification system to Stadler et al's invention to warn a patient of heart dysfunction.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

Art Unit: 3762

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571)272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


GEORGE R. EVANISKO
PRIMARY EXAMINER

9/30/15

MWK